UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,649	07/01/2003	**Chris Rundfeldt**	HUBR-1221	2085

24972 7590 02/26/2009
FULBRIGHT & JAWORSKI, LLP
666 FIFTH AVE
NEW YORK, NY 10103-3198

EXAMINER	
KANTAMNENI, SHOBHA	
ART UNIT	**PAPER NUMBER**
1617	
MAIL DATE	**DELIVERY MODE**
02/26/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/611,649	RUNDFELDT ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2008*.

2a)☒ This action is FINAL. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,8-13,15,17,18 and 20-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *1-4,6,8-13,15,17-18,20-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/12/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to applicant's response filed on 12/16/2008.

Claims 1-4, 6, 8-13, 15, 17-18, 20-23 are examined herein.

Applicant's arguments with respect to the rejections made in the previous office action dated 06/24/2008 have been considered, but not found persuasive. All the rejections of record are MAINTAINED. See under response to arguments.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitations, "sympathomimetic amine, xanthine derivative, and adrenal stimulant" in claim 20, render claim 20 herein indefinite. The recitations, "sympathomimetic amine, xanthine derivative, and adrenal stimulant" are not clearly defined in the specification. Hence, one of ordinary skill in the art could not ascertain and interpret the metes and bounds of the patent protection desired as to what compounds are encompassed by the recitations "sympathomimetic amine, xanthine derivative, and adrenal stimulant" herein. For example, one of ordinary skill in the art would clearly recognize that many widely varying groups could possibly substituting the xanthine herein would read on the "derivative" of xanthine.

Given the fact that any significant structural variation to a compound would be reasonably expected to alter its properties, e.g., physical, chemical, physiological effects and functions. It is unclear and indefinite as to the compounds encompassed by the recitations "sympathomimetic amine, xanthine derivative, and adrenal stimulant" herein.

Response to Arguments

Applicant argues that the terms “sympathomimetic amine”, “adrenal stimulant" are commonly used in medicine, and a person skilled in the art know which derivatives of xanthine are suitable for a medical use. These arguments have been considered, but not found persuasive. It is pointed out that for example, one of ordinary skill in the art would clearly recognize that many widely varying groups could possibly substituting the xanthine herein would read on the "derivative" of xanthine. It is not clear which of these derivative would be useful for medical use because any significant structural variation to a compound would be reasonably expected to alter its properties, e.g., physical, chemical, physiological effects and functions. Accordingly, is unclear and indefinite as to the compounds encompassed by the recitations "sympathomimetic amine, xanthine derivative, and adrenal stimulant" herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6, 8-13, 15, 17-18, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ehinger et al. (NAUNYN-SCHMIEDEBERG'S ARCHIVES OF PHARMACOLOGY, vol. 363, no.4 Supplement, 2001, page R85, XP009019486 42nd Spring Meeting of the German Society for Experimental and Clinical Pharmacology and Toxicology; Mainz, Germany; March 13-15, 2001, PTO-1449).

Ehinger et al. disclose the employment of AWD 12281 ((N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide) to treat atopic dermatitis. Experiments with toluene-2,4-diisocyanate (TDI)-sensitized mice was disclosed. TDI challenged mice were treated by topically applying AWD 12281 (0.1-3 %) i.e after an allergic challenge. Ehinger et al. discloses the use of AWD 12281 to treat atopic dermatitis. In some of the experiments with TDI-sensitized mice, the AWD was applied topically once or thrice in 24 hours. See the entire paper.

Ehinger et al. do not explicitly teach that (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide is administered to mice for the first time after an allergic challenge.

It would have been obvious to a person of ordinary skill in the art at the time of invention to administer (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide for the first time after an allergic challenge with reasonable expectation of treating atopic dermatitis because according to Ehinger et al. (N-3,5-

dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide is known to treat allergic skin diseases such as atopic dermatitis.

It would have been obvious to a person of ordinary skill in the art at the time of invention to administer (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide up to 48 h after an allergic challenge.

One of ordinary skill in the art at the time of invention would have been motivated to the particular treatment regimen i.e administer (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide for the first time after an allergic challenge, and to administer (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide up to 48 h after an allergic challenge because the optimization of result effect parameters e.g., dosage range, dosing regimens, dosing duration is obvious as being within the skill of the artisan, involving merely routine skill in pharmaceutical art.

Response to Arguments

Applicant argues that "Ehinger, however only discloses the use of AWD 12-281 after an allergic challenge in addition to the treatment with AWD 12-231 before an allergic challenge, in view of Ehinger, the skilled artisan would not have had any motivation and no reasonable expectation of success to administer AWD 12.-281 solely for the first time after an allergic challenge. In contrast, Ehinger confirmed the general prejudice of the skilled person that :for treatment of atopic dermatitis with a PDE4 inhibitor, the PDE4 inhibitor must at least in part be administered before an allergic challenge." These arguments have been considered, but not found persuasive because

the arguments are not in commensurate in scope with the instant claims. The instant method is drawn to employing AWD 12-281 in treating allergic skin disease, and not to employing a PDE4 inhibitor. It is pointed out that it is irrelevant if PDE4 inhibitor, cilomilast works in the method herein, since the structure of cilomilast is very different from the AWD 12-281 employed in the method herein.

Ehinger discloses the use of AWD 12-281 to treat atopic dermatitis. In some of the experiments with TDI-sensitized mice the AWD was applied topically once or thrice in 24 hours. In that case, "two hours after first treatment, the allergic reaction was challenged by administration of TDI onto the ears". Thus, AWD 12281 was also applied after TDI challenge.

It would have been obvious to a person of ordinary skill in the art at the time of invention to administer (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide for the first time after an allergic challenge with reasonable expectation of treating atopic dermatitis because 1) according to Ehinger (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide is known to treat allergic skin diseases such as allergic dermatitis, and further 2) the optimization of result effect parameters e.g., dosage range, dosing regimens, dosing duration is obvious as being within the skill of the artisan, involving merely routine skill in pharmaceutical art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20-21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ehinger et al. as applied to claims 1-4, 6, 8-13, 15, 17-18, and 22 above, in view of Winger (US 5,767,095, PTO-892).

Ehinger et al. is as discussed above.

Ehinger et al. does not teach the employment of a pharmaceutical agent, corticosteroid in combination with AWD 12281 in the method of treating atopic dermatitis.

Winger teaches that corticosterioids are known for the treatment of canine atopic dermatitis. See column 25, lines 19-22.

It is generally considered *prima facia* obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by recited teachings of Ehinger and Winger the instant claims contain two compounds used for treatment of skin condition such as atopic dermatitis. *In re Kerkohoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Response to Arguments

Applicant argues that "Claim 20 differs from Ehinger with respect to at least two features. Firstly, Ehinger does not disclose the use of a pharmaceutical combination, i.e. of a corticosteroid in combination with AWD 12-281, but only the use of AWD 12-281

alone. Furthermore, since claim 20 refers back to claim 1, the combination is only administered for the first time after an allergic challenge." These arguments have been considered, but not found persuasive. It is pointed out that applicant is arguing against a single reference when the rejection was based on combination of references.

Applicant argues that "Winger only disclose that corticosteroids are known for treatment of atopic dermatitis of dogs. Consequently, if the skilled artisan had combined the teachings of Ehinger and Winget he would not have arrived at the subject-matter of claims 20.--21 and 23." These arguments have been considered, but not found persuasive. It is generally considered *prima facia* obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by recited teachings of Ehinger and Winger the instant claims contain two compounds used for treatment of skin condition such as atopic dermatitis. *In re Kerkohoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6, 8-13, 15, 17-18, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baumer et al. (European Journal of Pharmacology, 446, 2002, pages 195-200, PTO-1449).

Baumer et al. disclose the employment of AWD 12-281 ((N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide) to treat allergic dermatitis in mice. To obtain an allergic dermatitis, BALB/c mice were sensitized to toluene-2,4-diisocyanate (TDI). TDI challenged mice were treated by topically applying AWD 12281 (0.1-3 %). It is disclosed that AWD 12-281 inhibited the ear swelling significantly 8, 16, 24, and 48 h. See abstract; page 196, right-hand column, paragraph 2-page 197, right-hand column, paragraph 1; page 198, left-hand column, last paragraph-page 199, paragraph 1.

Baumer et al. do not explicitly teach that (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide is administered to mice for the first time after an allergic challenge.

Baumer et al. do not explicitly teach that (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide is administered to mice up to 48 h after an allergic challenge.

It would have been obvious to a person of ordinary skill in the art at the time of invention to administer (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide for the first time after an allergic challenge with reasonable expectation of treating atopic dermatitis because according to Baumer et al. (N-3,5-

dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide is known to treat allergic skin diseases such as allergic dermatitis.

It would have been obvious to a person of ordinary skill in the art at the time of invention to administer (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide up to 48 h after an allergic challenge.

One of ordinary skill in the art at the time of invention would have been motivated to the particular treatment regimen i.e administer (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide after an allergic challenge, and to administer (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide up to 48 h after an allergic challenge because the optimization of result effect parameters e.g., dosage range, dosing regimens, dosing duration is obvious as being within the skill of the artisan, involving merely routine skill in pharmaceutical art.

Response to Arguments

Applicant argues that "It is respectfully submitted that the skilled artisan would not have thought of administering AWD 12-281 only for the first time after an allergic challenge since he already knew that other PDE4 inhibitors, such as cilomast, do not show any effect if they are administered solely for the first time after an allergic challenge. These arguments have been considered, but not found persuasive because the arguments are not in commensurate in scope with the instant claims. The instant method is drawn to employing AWD 12-281 in treating allergic skin disease, and not to employing a PDE4 inhibitor. It is pointed out that it is irrelevant if PDE4 inhibitor,

cilomilast works in the method herein, since the structure of cilomilast is very different from the AWD 12-281 employed in the method herein.

It would have been obvious to a person of ordinary skill in the art at the time of invention to administer (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide for the first time after an allergic challenge with reasonable expectation of treating atopic dermatitis because 1) according to Baumer et al. (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide is known to treat allergic skin diseases such as allergic dermatitis, and further 2) the optimization of result effect parameters e.g., dosage range, dosing regimens, dosing duration is obvious as being within the skill of the artisan, involving merely routine skill in pharmaceutical art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6, 8-13, 15, 17-18, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofgen et al. (US 6, 251, 923, PTO-1449).

Hofgen et al. discloses hydroxyindoles of the Formula (I), including the instantly elected species (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide for the treatment of skin diseases such as psoriasis, keratosis,

atopic dermatitis (allergic dermatitis), eczema. See abstract; column 7, lines 25-34; column 10, EXAMPLE 1. Oily suspensions for topical application comprising other agents such as fatty acid esters is also taught. See column 8, lines 43-45.

Hofgen et al. do not explicitly teach that (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide is administered for the first time after an allergic challenge.

It would have been obvious to a person of ordinary skill in the art at the time of invention to administer (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide for the first time after an allergic challenge with reasonable expectation of treating atopic dermatitis because according to Hofgen et al. (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide is known to treat allergic skin diseases such as atopic dermatitis, eczema.

It would have been obvious to a person of ordinary skill in the art at the time of invention to administer (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide up to 48 h after an allergic challenge.

One of ordinary skill in the art at the time of invention would have been motivated to the particular treatment regimen i.e administer (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide after an allergic challenge, and to administer (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide up to 48 h after an allergic challenge because the optimization of result

effect parameters e.g., dosage range, dosing regimens, dosing duration is obvious as being within the skill of the artisan, involving merely routine skill in pharmaceutical art.

Response to Arguments

Applicant argues that "In view of Hofgen, the skilled artisan would not have thought of administering AWD 12- 281 for the first time after the allergic challenge, since the skilled artisan would know that other PDE4 inhibitors, such as cilomast do not show any effect if these inhibitors are only administered for the first time after an allergic challenge." These arguments have been considered, but not found persuasive because the arguments are not in commensurate in scope with the instant claims. The instant method is drawn to employing AWD 12-281 in treating allergic skin disease, and not to employing a PDE4 inhibitor. It is pointed out that it is irrelevant if PDE4 inhibitor, cilomilast works in the method herein, since the structure of cilomilast is very different from the AWD 12-281 employed in the method herein.

It would have been obvious to a person of ordinary skill in the art at the time of invention to administer (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide for the first time after an allergic challenge with reasonable expectation of treating atopic dermatitis because 1) Hofgen et al. discloses topical administration of hydroxyindoles of the Formula (I), including the instantly elected species (N-3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide for the treatment of skin diseases such as psoriasis, keratosis, atopic dermatitis (allergic dermatitis), and further 2) the optimization of result effect parameters

e.g., dosage range, dosing regimens, dosing duration is obvious as being within the skill of the artisan, involving merely routine skill in pharmaceutical art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6, 8-13, 17-18, are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27-29, 36-38, and 69-84 of co-pending Application No. 10/856034. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a method of treating skin disease comprising topically administering N-(3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide,

and '034 is drawn to a method of treating atopic dermatitis comprising administering a compound, N-(3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide. The application '034 does not specifically teach the topical administration of the compound in the method therein. It would have been obvious to the person of ordinary skill in the art at the time of invention to administer topically to a subject a therapeutically effective amount of N-(3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3yl]-2-oxoacetamide with reasonable expectation of treating a skin disorder. Further, topical administration of compounds is well known for treating skin disorders, and '034 discloses that the compounds therein can be administered topically. See page 14 of '034.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to applicant's argument: Applicant's arguments have been considered, but not found persuasive as discussed above.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period, will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Tuesday-Friday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D
Patent Examiner
Art Unit : 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617